UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

STEPHEN G. PARRA ELAINE PARRA	CIVIL ACTION
VERSUS	NO. 16-14696
COLOPLAST CORP.	SECTION "R" (2)

ORDER AND REASONS

Before the Court is defendant Coloplast Corp.'s motion to dismiss plaintiffs Stephen G. Parra and Elaine Parra's lawsuit.[1] For the following reasons, the Court GRANTS defendant's motion.

I. BACKGROUND

This is a Louisiana law products liability case. According to plaintiffs' petition, defendant Coloplast manufactures and distributes the Coloplast Titan, an inflatable penile prosthesis.[2] The Titan is a self-contained, fluid-filled system designed to allow those suffering from erectile dysfunction to achieve an erection.[3] Plaintiff Stephen Parra suffered from organic erectile dysfunction as a result of the prostate cancer treatment he received, and

1 R. Doc. 9.
2 R. Doc. 1-1 at 1 ¶ 5.
3 *Id*. at 1-2 at ¶¶ 5-8.

sought a penile implant.[4] Plaintiff had surgery to implant the Titan prosthesis on or about April 28, 2015.[5]

According to Parra, his initial recovery was unremarkable, but he soon began to experience multiple, painful problems with the prosthesis, including repeated spontaneous inflations, without release.[6] The prosthesis eventually stopped working entirely, and plaintiff alleges that he will need to have surgery to either repair or replace the prosthesis.[7] Plaintiff also alleges that the Titan's malfunction has caused permanent nerve damage and other damages which will require additional future surgeries.[8]

On April 27, 2016, plaintiff and his wife Elaine Parra filed a petition in the Civil District Court for the Parish of Orleans against Coloplast.[9] On August 15, 2016, plaintiffs filed a supplemental and amending petition.[10] The petition alleges that Coloplast was negligent and that the Titan implant was defective and unreasonably dangerous under the Louisiana Products Liability Act (LPLA), due to defective design and/or construction,

---

4 *Id.* at 2 ¶ 8.
5 *Id.* ¶ 9.
6 *Id.* ¶ 10.
7 *Id.* ¶ 11.
8 *Id.*
9 *Id.* at 1.
10 *Id.* at 5.

inadequate warnings, and for failure to comply with an express warranty.[11] Stephen Parra seeks damages including, but not limited to, past, present and future pain and suffering; past, present and future mental suffering; past, present and future loss of wages and/or loss of earning capacity; past, present and future medical expenses; permanent disability; loss of enjoyment of life; and permanent disfigurement and scarring.[12] Plaintiff Elaine Parra also seeks damages for loss of consortium, service, and society as a result of the physical and emotional injuries, damages, and mental and physical trauma sustained by her husband Stephen.[13]

On September 14, 2016, defendant removed the case to this Court on the basis of diversity jurisdiction.[14] On October 12, 2016, defendant filed this motion to dismiss, arguing that plaintiffs' state law claims are preempted pursuant to the Medical Device Amendments (MDA), 21 U.S.C. § 360k, to the Federal Food, Drug & Cosmetic Act (FFDCA), 21 U.S.C. § 301, *et seq*.[15] Defendant additionally argues that plaintiffs' amended petition fails to state a claim to relief that is plausible on its face. Plaintiffs have not filed a response and do not oppose defendant's motion.

---

11 *Id*. at 2-3 ¶ 12.
12 *Id*. at 3 ¶ 13.
13 *Id*. ¶ 14.
14 R. Doc. 1.
15 R. Doc. 9.

II. LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the plaintiff pleads facts that allow the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. A court must accept all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff. *Gines v. D.R. Horton, Inc.*, 699 F.3d 812, 816 (5th Cir. 2012) (quoting *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007)). But a court is not bound to accept as true legal conclusions couched as factual allegations. *Iqbal*, 556 U.S. at 678.

A legally sufficient complaint must establish more than a "sheer possibility" that the plaintiff's claim is true. *Id*. It need not contain detailed factual allegations, but it must go beyond labels, legal conclusions, or formulaic recitations of the elements of a cause of action. *Id*. (citing *Twombly*, 550 U.S. at 555). In other words, the face of the complaint must contain enough factual matter to raise a reasonable expectation that discovery will reveal evidence of each element of the plaintiff's claim. *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 257 (5th Cir. 2009). If there

are insufficient factual allegations to raise a right to relief above the speculative level, *Twombly*, 550 U.S. at 555, or if it is apparent from the face of the complaint that there is an insuperable bar to relief, *see Jones v. Bock*, 549 U.S. 199, 215 (2007); *Carbe v. Lappin*, 492 F.3d 325, 328 n.9 (5th Cir. 2007), the claim must be dismissed.

III. DISCUSSION

Plaintiffs bring their claims pursuant to the LPLA. The LPLA provides the exclusive remedy against a manufacturer for damages caused by its product. La. Stat. Ann. § 9:2800.52. A plaintiff may not recover under any theory of liability that is not set forth in the LPLA. *Id.*; *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 261-62 (5th Cir. 2002). The statute provides that a manufacturer "shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." La. Stat. Ann. § 9:2800.54(A).

A product is unreasonably dangerous for the purposes of the statute "if and only if" it is unreasonably dangerous: (1) in construction or composition, (2) in design, (3) because of inadequate warning, or (4) because of

nonconformity to an express warranty. *Id*. at § 2800.54(B)(1–4). Thus, the LPLA limits the plaintiff to four theories of recovery: construction/composition defect, design defect, inadequate warning, and breach of express warranty.

"While the statutory ways of establishing that a product is unreasonably dangerous are predicated on principles of strict liability, negligence, or warranty, respectively, neither negligence, strict liability, nor breach of express warranty is any longer viable as an independent theory of recovery against a manufacturer." *Jefferson v. Lead Indus. Ass'n, Inc.*, 930 F. Supp. 241, 245 (E.D. La. 1996) *aff'd*, 106 F.3d 1245 (5th Cir. 1997) (citing *Automatique New Orleans, Inc. v. U-Select-It, Inc.*, 1995 WL 491151 at *3 n.2 (E.D. La. Aug. 15, 1995) (no independent negligence claim); J. Kennedy, A Primer on the Louisiana Products Liability Act, 49 La. L. Rev. 565, 589-90 (1989)). Similarly, breach of implied warranty is unavailable as a theory of recovery for personal injury. *Id*.

A. Preemption

Defendant first argues that plaintiffs' LPLA claims are preempted by the Medical Device Amendments, 21 U.S.C. § 360k, to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301, *et seq*. Defendant concedes that it

owns and manufactures the Titan.[16] The Titan is a Class III device under the FFDCA and is subject to the FDA's pre-market approval process. The Court has taken judicial notice of the FDA's website, which indicates that the Titan underwent the FDA's pre-market approval process under the FFDCA.[17] *See Scianneaux v. St. Jude Medical S.C., Inc.*, 961 F. Supp. 2d 808, 812 (E.D. La. 2013) (taking judicial notice of the FDA's website). The website further indicates that the FDA has approved several modifications to the design, manufacturing process, and labeling of the Titan.[18] *See Spier v. Coloplast Corp.*, 121 F. Supp. 3d 809, 815 (E.D. Tenn. 2015) ("It is clear that the Titan Prosthesis received and has since maintained PMA status.").

The MDA expressly preempts state law claims against manufacturers when the effect is to establish "safety or effectiveness" standards that are "different from, or in addition to" the requirements for pre-market approved products under the FFDCA. 21 U.S.C. § 360k. Therefore, to the extent that state law claims impose duties on Class III PMA devices that are different or in addition to the requirements set forth by the FDA, they are necessarily

---

[16] R. Doc. 9-1 at 7.

[17] FDA database of premarket approvals, accessible at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm.

[18] FDA page for the Titan, accessible at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000006.

preempted. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 329-30 (2008). However, "parallel" state actions—state law claims that are premised on violations of FDA regulations—are permitted. *Id.* at 330; *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

Plaintiffs, therefore, may bring suit under the LPLA only if they can show that it was a violation of FDA regulations that rendered the Titan "unreasonably dangerous." *Scianneaux*, 961 F. Supp. 2d at 812 (quoting *Riegel*, 552 U.S. at 330). Moreover, the allegations that Coloplast violated FDA regulations must satisfy the pleading requirements of *Twombly*. *See Bass v. Stryker Corp.*, 669 F.3d 501, 509-10 (5th Cir. 2012) (affirming the conclusion that "to plead a parallel claim successfully, a plaintiff's allegations that the manufacturer violated FDA regulations must meet the *Twombly* plausibility standard," and applying that standard to plaintiff's claim). Although a formal finding of a violation by the FDA is not required, *id.* at 509 (citing *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 772 (5th Cir. 2011)), the plaintiff must at least "specif[y] with particularity what went wrong in the manufacturing process and cite[] the relevant FDA manufacturing standards [the defendant] allegedly violated." *Id.* at 510 (quoting *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011)).

The Court addresses plaintiffs' manufacturing and design defect claims first. Here, plaintiffs' petition makes no mention of anything that went wrong in the manufacturing process and similarly mentions no violation of any federal design or manufacturing requirements.[19] Therefore, plaintiffs make no argument explaining how the design, manufacture, or sale of the Titan deviated from FDA requirements. The Fifth Circuit explained in *Rodriguez v. American Medical Systems, Inc.* that failure to connect an alleged violation of federal design or manufacturing requirements to a state law design or manufacturing defect is fatal to those claims. 597 F. App'x 226, 230 (5th Cir. 2014) (finding plaintiff's state law claims regarding Class III device not parallel and therefore preempted because plaintiff failed to allege a "violation of any federal requirement relating to design or manufacturing of the implant," and failed to "allege a specific defect in the manufacturing process or design, any deviation from the FDA-approved design or manufacturing processes, or any causal connection between a violation of federal requirements and [plaintiff's] injuries."); *Spier*, 121 F. Supp. 3d at 816 (holding that "[p]laintiff's complaint does not suggest defendant has failed to conform to the FDA requirements prescribed by its premarket approval or

[19] In fact, neither plaintiffs' original petition nor their supplemental petition makes any mention of the FDA at all.

has deviated from or violated any federal statute or regulation . . . . Therefore, the Court finds the exception for parallel claims does not apply, . . . and the claim is preempted by the MDA."). The fatal flaw identified by *Rodriguez* applies here as well. Thus, plaintiffs' petition does not plead a parallel manufacturing or design defect action and these claims are preempted by the MDA.

Plaintiffs' failure to warn claim is similarly preempted. As above, the Court takes judicial notice that the FDA has approved the labeling and specific warning instructions for the Titan. *See also Spier*, 121 F. Supp. 3d at 817 ("[T]he FDA has already approved specific warnings and instructions for the Titan Prosthesis."). Plaintiffs' petition makes no mention of the approved FDA warnings and contains no allegations that defendant has deviated from these accepted warnings and instructions in any manner. As such, plaintiffs' failure to warn claim seeks to impose liability for defendant's failure to include warnings or instructions that are not required by federal law. Therefore, the claim is not parallel to FDA requirements but is in addition to them, and is preempted.[20] *See Riegel*, 552 U.S. at 329-30; *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931 (5th Cir. 2006) (affirming

[20] Even if plaintiffs' claims were not preempted, it would not survive a motion to dismiss because plaintiffs' claims fail to satisfy the plausibility requirement of *Twombly*. *See Bass*, 669 F.3d at 509-10.

district court's ruling that plaintiff's LPLA failure to warn claim was preempted because FDA had approved warnings and instructions); *Spier*, 121 F. Supp. 3d at 817.

B. Breach of Warranty LPLA Claim

Plaintiffs' petition also asserts a breach of express warranty claim under the LPLA. As the Fifth Circuit has noted, breach of express warranty claims can survive MDA preemption if the warranty arises "'from the representations of the parties and are made as the basis of the bargain between them' and may 'not necessarily interfere with the operation of the PMA.'" *Gomez*, 442 F.3d at 932 (quoting *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997). But if the warranty at issue contradicts the FDA's requirements, *Spier*, 121 F. Supp. 3d at 818, or the warranty is intertwined with the FDA's standards, the claim will be preempted. *Gomez*, 442 F.3d at 932.

Here, plaintiffs have failed to plead their express warranty claim with enough particularity to allow the Court to determine if the claim is preempted. *See Spier*, 121 F. Supp. 3d at 818-19. This failure does not affect the outcome, however, because even if this claim is not preempted, it fails to establish a plausible breach of express warranty claim under *Twombly*. As discussed above, in addition to pleading a violation of FDA regulations, a

plaintiff must plead facts in support of each element of a claim under the LPLA, including "(1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that the characteristic made the product unreasonably dangerous in one of the four ways provided in the statute; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else." *Jefferson*, 930 F. Supp. at 245 (citing La. Stat. Ann. § 9:2800.54).

Plaintiffs' petition does no more than recite the bare elements of an LPLA claim. *See Iqbal*, 556 U.S. at 678. Further, plaintiffs' petition does not set forth the necessary factual allegations to plead a sufficient breach of express warranty claim under the LPLA.

To establish a breach of express warranty claim, a plaintiff must show that (1) there was an express warranty made by the manufacturer about the product; (2) the express warranty induced the plaintiff to use the product; and (3) the plaintiff's damage was proximately caused because the express warranty was untrue. La. Stat. Ann. § 9:2800.58; *see also Caboni v. Gen. Motors Corp.*, 278 F.3d 448, 452 (5th Cir. 2002). Here, plaintiffs' petition makes no such allegations. The petition does not allege that the supposed express warranty induced plaintiff to use the Titan, and beyond the legal

conclusion that an express warranty existed, the petition does not allege with specificity anything about the express warranty, including when it was made and who made it. *See Robertson v. AstraZeneca Pharmaceuticals, LP*, No. 15-438, 2015 WL 5823326, at *5 (E.D. La. Oct. 6, 2015) (dismissing breach of express warranty claim under LPLA because plaintiff failed to "make more than a general reference to [an express warranty]"); *Flournoy v. Johnson & Johnson*, No. 15-5000, 2016 WL 6474142, at *3-4 (E.D. La. Nov. 2, 2016) (stating that plaintiffs' LPLA breach of express warranty claim fails to meet the requisite pleading standard because "it does not identify the contents of any warranty or how identify how that warranty induced the Plaintiff to use the product").

In conclusion, plaintiffs' breach of express warranty claim contains insufficient factual allegations to raise a right to relief above the speculative level. *Twombly*, 550 U.S. at 555. Rule 8 of the Federal Rules of Civil Procedure "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Gulf Coast Hotel-Motel Ass'n v. Miss. Gulf Coast Golf Course Ass'n*, 658 F.3d 500, 504 (5th Cir. 2011) (citing Iqbal, 556 U.S. at 678). Therefore, to the extent that plaintiffs' breach of express warranty claim is not preempted by the MDA, it must be dismissed for failure to state a claim.

Defendant's motion to dismiss asks the Court to dismiss plaintiffs' petition with prejudice.[21] Plaintiffs did not respond to defendant's motion, and therefore present no argument against a dismissal with prejudice. Because plaintiffs have already had one opportunity to amend their petition and continue to provide nothing more than conclusory allegations, the petition will be dismissed with prejudice. *See Scianneaux*, 961 F. Supp. 2d at 814.

IV. CONCLUSION

For the foregoing reasons, defendant's motion to dismiss is GRANTED, and plaintiffs' petition is DISMISSED WITH PREJUDICE.

New Orleans, Louisiana, this 3rd day of January, 2017.

SARAH S. VANCE
UNITED STATES DISTRICT JUDGE

[21] R. Doc. 9-1 at 1.